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10/598,215	08/21/2006	Dilip K. Nakhasi	0803-0111.03	1259

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EXAMINER	
GWARTNEY, ELIZABETH A	

ART UNIT	PAPER NUMBER
1781	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,215	NAKHASI ET AL.	
	Examiner	Art Unit	
	ELIZABETH GWARTNEY	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/13/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed January 13, 2010 has been entered. Claims 1-39 are pending.

2. The previous claim objections and 112,2nd Paragraph rejections have been withdrawn in light of applicant's amendments made January 13, 2010.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 19 recite "having interexchanged said first fatty acid chains and said second fatty acid chains that vary randomly from glycerol structure to glycerol structure." While the Specification as originally filed states that "[t]ypically, the interesterification is a reaction to or toward complete randomization. . ." there is no explicit or implicit support in the specification wherein an interesterified structured lipid component has interexchanged said first fatty acid

chains and said second fatty acid chains that vary randomly from glycerol structure to glycerol structure.

6. Claims 1-18 and 29-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the recitation "said structured lipid component is a reaction product of an interesterification reactant charge....of a medium chain triglyceride having first fatty acid chains that are from C6 to C12 in ***length, randomization reacted with*** between about 15 and about 85 weight percent. . ." renders the claim indefinite. It is not clear what properties are encompassed by the phrase "randomization reacted with about 15 and about 85 weight percent" or what the term "randomization" refers to in the context of the claim limitation.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama (US 6,827,963) in view of Wester et al. (US 6,589,588) and St-Onge et al. ("Phytosterols and Human Lipid Metabolism: Efficacy, Safety, and Novel Foods")

Regarding claims 1, 6-10 and 18, Aoyama discloses an oil composition for reducing lipids in blood comprising a synthesized triglyceride wherein a medium chain fatty acid having 8 to 10 carbons atoms is combined at the first and third carbons and a long chain fatty acid having 16 to 18 carbons atom is combined at the second carbon of the triglyceride (Abstract, C4/L40-51). Specifically, Aoyama discloses synthesized triglyceride made by mixing 40% trioleilin with 60% caplyric acid (C10/Example 3), 40% sunflower oil rich in oleic acid with 60% caprylic acid (C8/Example 2), or 50% tricarylin with 50% oleic acid (C8/Example 1).

While Aoyama discloses directed interesterification to prepare the triglycerides of Example 1 and 3, the reference also discloses the use of chemical, i.e. random, interesterification (C8/L18-23). Given Aoyama discloses triglycerides prepared by random interesterification,

intrinsically the structured lipid component would have randomly interexchanged said first fatty acid chains and said second fatty acid chains that vary randomly from glycerol structure to glycerol structure.

Aoyama does not explicitly disclose that the synthesized triglyceride is a reaction product of an interesterification reactant charge, however, it is noted that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in Thorpe, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.)

Further, Aoyama fails to disclose that the oil composition comprising between 4% and 20%, up to about 12% or about up to 10% of a phytosterol ester component.

Wester et al. teach the incorporation of phytosterol esters into specific foods including cooking oil (Abstract, C5/L35-38, C9/L4-8). Wester et al. teach that plant sterol help reduce serum cholesterol levels in the body by reducing the absorption of cholesterol from the digestive tract (C1/L13-20).

St-Onge et al. teach that doses as low as 0.8 g/day are efficacious in lowering total cholesterol and LDL-cholesterol concentrations (p. 369/Dosage/paragraph 1).

Aoyama and Wester et al. are combinable because they are concerned with the same field of endeavor, namely, fat and oil components. Given Wester et al. teach that it was known to

incorporate phytosterol esters into cooking oil, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated phytosterol ester, as taught by Wester, into the oil composition of Aoyama to enhance the health benefits, i.e. cholesterol reducing efficacy, of the oil.

Regarding the amount of phytosterol ester, given St-Onge et al. teach that doses as low as 0.8 g/day of phytosterol ester are efficacious, since the amount of phytosterol ester ingested is dependent on the amount of phytosterol ester in the oil composition and the amount of oil composition consumed, i.e. serving size, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the phytosterol ester into the oil composition of Aoyama in an amount adequate for optimal cholesterol reducing efficacy in a given serving size and arrive at the present invention.

Regarding claims 2-5, 30-33 and 37, modified Aoyama discloses all of the claim limitations as set forth above. While modified Aoyama discloses an oil composition effective at reducing blood lipid and cholesterol levels, the references do not explicitly disclose that the oil composition, when ingested by a hypercholesterolemic individual, reduces the LDL cholesterol level of said individual by at least about 10%, reduces the total cholesterol level of said individual by at least about 8% or by at least about 12%, does not significantly reduce the HDL cholesterol level of said individual, and reduces adipose mass of said individual.

Given modified Aoyama discloses an oil composition identical to that presently claimed, it is clear that the composition would display the recited health benefits.

Regarding claims 11-13 and 35-36 modified Aoyama discloses all of the claim limitations as set forth above. Given Aoyama discloses a synthesized triglyceride component

identical to that presently claimed, it is clear that it would intrinsically display the recited viscosity and smoke point properties.

Regarding claim 14, modified Aoyama discloses all of the claim limitations as set forth above. Wester et al. also teach a phytosterol ester component with no phytostanol (*see* sterol or stanol fatty acid ester compositions - C3/L62-63).

Regarding claim 15, modified Aoyama discloses all of the claim limitations as set forth above. Regarding the method limitations recited in 15, it is noted that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in Thorpe, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.).

Regarding claims 16-17 and 38, modified Aoyama discloses all of the claim limitations as set forth above. Given modified Aoyama discloses an oil composition identical to that presently claimed, it is clear that the oil composition would intrinsically display the recited storage stability and sensory characteristics.

Regarding claim 19, Aoyama discloses a method of making an oil composition for reducing blood lipid levels, comprising: (a) providing a medium chain triglyceride having carbon chain lengths of between C6 and C10 (i.e. caprylic acid); (b) providing sunflower oil having carbon chain lengths of C18 (i.e. high oleic acid); (c) mixing 40% sunflower rich in oleic

acid, 60% caprylic acid and Lypozyme IM60 enzyme together; (d) and reacting at 50°C for 20 hours to interesterify the oil.

While Aoyama discloses directed interesterification to prepare the triglycerides of Example 1 and 3, the reference also discloses the use of chemical, i.e. random, interesterification (C8/L18-23). Given Aoyama discloses triglycerides prepared by random interesterification, intrinsically the structured lipid component would have randomly interexchanged said first fatty acid chains and said second fatty acid chains that vary randomly from glycerol structure to glycerol structure.

Aoyama fails to disclose combining the oil composition with up to 20% of a phytosterol ester component.

Wester et al. teach the incorporation of phytosterol esters into specific foods including cooking oil (Abstract, C5/L35-38, C9/L4-8). Wester et al. teach that plant sterol help reduce serum cholesterol levels in the body by reducing the absorption of cholesterol from the digestive tract (C1/L13-20).

St-Onge et al. teach that doses as low as 0.8 g/day are efficacious in lowering total cholesterol and LDL-cholesterol concentrations (p. 369/Dosage/paragraph 1).

Aoyama and Wester et al. are combinable because they are concerned with the same field of endeavor, namely, fat and oil components. Given Wester et al. teach that it was known to incorporate phytosterol esters into cooking oil, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated phytosterol ester, as taught by Wester et al., into the oil composition of Aoyama to enhance the health benefits, i.e. cholesterol reducing efficacy, of the oil.

Regarding the amount of phytosterol ester, given St-Onge et al. teach that doses as low as 0.8 g/day of phytosterol ester are efficacious, since the amount of phytosterol ester ingested is dependent on the amount of phytosterol ester in the oil composition and the amount of oil composition consumed, i.e. serving size, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the phytosterol ester into the oil composition of Aoyama in an amount adequate for optimal cholesterol reducing efficacy in a given serving size and arrive at the present invention.

Given modified Aoyama discloses an oil composition identical to that presently claimed, since Aoyama discloses a synthesized triglyceride for reducing blood lipid levels and Wester et al. teaches phytosterol esters are effective for reducing serum cholesterol and LDL-cholesterol concentrations, it is clear that the oil composition would intrinsically be consumable and reduce atherogenic risk for consuming individuals.

Regarding claims 20-21 and 39, modified Aoyama discloses all of the claim limitations as set forth above. Given modified Aoyama discloses an oil composition identical to that presently claimed, it is clear that it would intrinsically display the recited viscosity and smoke point properties.

Regarding claims 22-25, modified Aoyama discloses all of the claim limitations as set forth above. Aoyama also discloses using the oil composition for reducing lipids in blood by taking the synthesized triglyceride as an effective component in an amount of 1 to 60 grams daily. Given modified Aoyama discloses an oil composition identical that presently claimed, since Aoyama discloses ingesting an oil composition for healthful benefit, it is clear that the oil

composition of modified Aoyama would be ingested to promote the recited health and nutritional benefits in an individual.

Regarding claims 26-28, modified Aoyama discloses all of the claim limitations as set forth above. given St-Onge et al. teach that doses as low as 0.8 g/day of phytosterol ester are efficacious, since the amount of phytosterol ester ingested is dependent on the amount of phytosterol ester in the oil composition and the amount of oil composition consumed, i.e. serving size, it would have been obvious to one of ordinary skill in the art at the time of the invention to have administered the oil composition of modified Aoyama, at any level, including those recited, given phytosterol ester in an amount adequate for optimal cholesterol reducing efficacy.

Regarding claim 29, modified Aoyama discloses all of the claim limitations as set forth above. Given modified Aoyama discloses an oil composition identical to that presently claimed, it is clear that that the oil composition, when ingested by a phypercholesterolemic individual, would intrinsically reduce the LDL cholesterol levels of said individual by at least about 15% and decrease atherogenic risk in individuals.

Regarding claim 34, modified Aoyama discloses all of the claim limitations as set forth above. Regarding the amount of phytosterol ester, given St-Onge et al. teach that doses as low as 0.8 g/day of phytosterol ester are efficacious, since the amount of phytosterol ester ingested is dependent on the amount of phytosterol ester in the oil composition and the amount of oil composition consumed, i.e. serving size, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the phytosterol ester into the oil composition of Aoyama in an amount adequate for optimal cholesterol reducing efficacy in a given serving size and arrive at the present invention.

Response to Arguments

10. Applicant's arguments filed January 13, 2010 have been fully considered but they are not persuasive.

Applicants have amended the claims to include a randomized structure lipid product. Applicants argue that Aoyama fails to teach any such randomized interesterified product.

It is noted that applicants define randomization as a chemical reaction whereby individual fatty acid structures at positions of the triglyceride being interesterified are interchanged on the glycerol moiety ([0010]). Similarly, Aoyama discloses chemical interesterification (C8/L18-23). Therefore, it is the Examiner's position, given Aoyama discloses a chemical interesterification method substantially similar to randomization described by applicant, that Aoyama discloses a triacylglycerol structure which has interchanged fatty acid moieties that vary from glycerol structure to glycerol structure.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH GWARTNEY whose telephone number is (571)270-3874. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794